

Response
Applicants: Bruce S. Ellingboe et al.
Serial Number: 09/963,878

Attorney Docket: CV0290US

REMARKS

Claims 1 and 3- 12 are pending. Claim 2 was previously canceled. Claims 1 and 3-5 were previously amended. Claims 6-12 are original. The application as filed supports all of the claims.

Rejections Under 35 U.S.C. 103

Claims 1, 3, 4 and 6-12 are finally rejected under 35 U.S.C. 103(a) as unpatentable over Dennehey in view of Abbott. These references do not render obvious the presently rejected claims. Dennehey does not teach or suggest a structure that oxygenates venous blood and transfers oxygenated venous blood to the patient, as required by claim 1 and the claims dependent thereon. The Dennehey blood processing system has no need for a blood oxygenator and a blood oxygenator would serve no purpose in the Dennehey system, because the Dennehey system processes a donor's blood and returns the processed blood to the donor without compromising the function of the donor's cardiopulmonary system (col. 16, line 25 – col. 20, line 5). By contrast, the Abbott cardioplegia delivery system delivers cardioplegic solution to the heart during open heart surgery and absolutely requires an oxygenator to supply the function of the patient's cardiopulmonary system. There is no suggestion in Dennehey or Abbott or in any of the other art of record to combine the teachings of these two references in the manner the Examiner proposes.

Neither Dennehey, Abbott nor any of the other references of record, disclose or suggest a disposable assembly further comprising a reservoir having an inlet connected to receive venous blood from the patient through a second of the positioned tubing lines or a component interface region further comprising a flow control clamp for controlling the flow of venous blood through the second tubing line to the reservoir, as required by claim 1 and the claims dependent thereon.

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More specifically, neither Dennehey nor Abbott includes any structure comprising a flow control clamp and, therefore, these references cannot possibly be combined in a manner required by these claims.

Dennehey discusses the advantages of peristaltic pumps to centralize pumping, valving and sensing operations (col. 1, lines 36-38, col. 23, line 2 – col. 26, line 4, *inter alia*) and does not teach or suggest the use of any other pump. The Abbott system uses (col. 5, lines 26-29, *inter alia*) a bladder pump that “advantageously reduces the shearing forces and potential damage to which blood might be subjected in other pumps, such as peristaltic pumps.” Accordingly, one of skill in this art, aware of the Abbott teaching against the use of peristaltic pumps and Dennehey’s preference for peristaltic pumps, would find no motivation to incorporate the Dennehey teachings into the Abbott disclosure or *vice versa*. Also, note the teachings of U.S. Pat. No. 5,820,579 to Plotkin (“Plotkin”), discussed further below, that also disfavor the use of bladder pumps. The Examiner points to no teaching or suggestion in any of the prior art of record that would supply for this divergence in teachings between Abbott and Dennehey, and the further negative teachings of Plotkin, discussed below in more detail. In addition, claims 3, 4 and 6-12 add further patentable features that Abbott and Dennehey do not show or suggest.

The Examiner states that, “claim limitations drawn to the functions of the blood circuit, the pump, the reservoir, flow control clamp, sensors ... have not been given patentable weight,” because they have not been “expressed as a ‘means’ for performing the specified function.” However, the Manual of Patent Examining Procedure (M.P.E.P.) clearly states:

There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and

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of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.

M.P.E.P. 2173.05(g) Functional Limitations.

In addition, Court of Appeals for the Federal Circuit (CAFC) in *Greenberg v. Ethicon Endo-Surgery Inc.*, 39 USPQ2d 1783, 1786 considered an element of a claim, a "detent mechanism," defined in terms of what it does. The CAFC noted:

Many devices take their names from the functions they perform. The examples are innumerable, such as 'filter,' 'brake,' 'clamp,' 'screwdriver,' or 'lock.' ... What is important is not simply that a 'detent' or 'detent mechanism' is defined in terms of what it does, but that the term, as the name for the structure, has a reasonably well understood meaning in the art.

Id., at 1785-86. Note that the term 'clamp,' considered acceptable by the Greenberg court, is among the terms that the Examiner has refused to consider in the examination of these claims.

Because the Examiner has failed to consider these claim limitations, these claims have not been fully searched and the grounds of rejection have not been clearly developed. M.P.E.P. 706.07 Final Rejection requires:

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched ... and the references fully applied. ...

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[A]ll outstanding grounds of rejection of record should be carefully reviewed, and ... must also be clearly developed ...

In refusing to give patentable weight to certain claim limitations, the Examiner required that "a functional recitation must be expressed as a 'means' for performing the specified function, as set forth in 35 USC 112, 6th paragraph." Note also that *Greenberg* commented on attempting to interpret a claim element as a "means-plus-function" element not recited in "means-plus-function" format:

First, the fact that a particular mechanism – here "detent mechanism" – is defined in functional terms is not sufficient to convert a claim element containing that term into a "means for performing a specified function" within the meaning of section 112(6). ...

Second, ... each [element] is ... claimed ... without the use of the term "means," in claim 1 ...

Finally, ... [i]n this case, ... the element in question did not use conventional "means-plus-function" language, no other element of the claim was in means-plus-function form, and nothing cited to us from the prosecution history or elsewhere suggests that the patentee intended to claim in that fashion.

Id.

To the extent that the Examiner has failed to consider these claim limitations, "a clear issue" has not been reached, the outstanding Final Rejection is improper and withdrawal thereof is in order. M.P.E.P. 706.07 (d) Final Rejection, Withdrawal of, Premature.

The Examiner also states, "Abbott specifically contemplates embodiments found in the Dennehey device and improves upon them," and the "examiner has found another reason for combining the references, namely the presence of the oxygenator in the Abbott device." The Examiner fails to support either of these

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conclusions either from teachings or suggestions in the art of record or based on knowledge available to one of ordinary skill in this art.

Applicants respectfully submit that claims 1, 3, 4 and 6-12 define an invention patentable over the cited references.

Claim 5 is rejected under 35 U.S.C. 103(a) as unpatentable over Dennehey in view of Plotkin, in view of Abbott. These references do not render obvious claim 5 as dependent on claim 1. Applicants repeat the discussions above regarding Dennehey and Abbott as equally pertinent.

Plotkin teaches away from the Abbott disclosure. Abbott recommends the use of a bladder pump. Plotkin denigrates the use of bladder pumps (col. 1, lines 59-67, *inter alia*), because they tend to be more mechanically complex and do not lend themselves to low cost manufacture for one-time disposable use. Plotkin states that increased blood trauma is experienced in bladder pumps due to the multiple check valves in the flow path and stagnant areas due to less than perfect chamber filling and ejection. Note the multiple check valves 84, 86, 88, 90, 92, 94 in the Abbott disposable cassette (Fig. 2 and the discussion in the specification, *inter alia*). Accordingly, one of skill in this art, aware of the Plotkin teachings against the use of bladder pumps, would find no motivation to incorporate the Plotkin teachings into the Dennehey or Abbott disclosures or *vice versa*.

There is no suggestion in Abbott, Dennehey or Plotkin or in any other art of record to combine these reference teachings and Plotkin does not supply for the deficiencies of the other two references. Applicants respectfully submit that claim 5 defines patentably over the cited references.

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Reply to the Examiner's "Response to Arguments"

The Examiner acknowledges (page 4, line 19 – page 5, line 1):

[O]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

Without pointing to any such required teaching, suggestion or motivation, the Examiner goes on to state (page 5, lines 7 – 9):

[N]othing in the Dennehey reference discourages an operator from adding an oxygenator to the blood processing assembly in order to provide more flexible processing operations.

The Examiner fails to explain what supposed "more flexible processing operations" would be derived by adding an oxygenator to the blood processing assembly of Dennehey and where the teaching, suggestion or motivation for such a modification is found the references themselves or in the knowledge generally available to one of ordinary skill in the art.

The Examiner cites *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992) supposedly to support the Final Rejection. However, in both *Fine* and *Jones*, the Court of Appeals for the Federal Circuit ("CAFC") reversed the Board of Patent Appeals and Interferences. Accordingly, both *Fine* and *Jones* support the position of Applicants, not that of the Final Rejection.

In *Fine*, the CAFC emphasized that:

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. ... It can satisfy this burden only by showing some objective teaching in the prior art that that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. ... This it has not done. The Board points to nothing in the cited

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references, either alone or in combination, suggesting or teaching
Fine's invention.

Fine, at 1598 - 1599, citations omitted. Note that the CAFC also stated, "The Board reiterated the Examiner's bald assertion that 'substitution of one type of detector for another ... would have been within the skill of the art,' but neither of them offered any support for or explanation of this conclusion." *Id.* Here, the Examiner has offered no support for or explanation of the conclusion that there is knowledge generally available to one of ordinary skill in this art to lead that individual to add an oxygenator to the Dennehey blood processing assembly supposedly to provide more flexible processing operations. As pointed out above, the Dennehey blood processing system has no need for a blood oxygenator and a blood oxygenator would serve no purpose in the Dennehey system, because the Dennehey system processes a donor's blood and returns the processed blood to the donor without compromising the function of the donor's cardiopulmonary system (col. 16, line 25 – col. 20, line 5, *inter alia*).

Jones is not on point with the present fact situation, because it involves a chemical case of "structural similarity" in which one ammonium salt was substituted for another in a known acid. In *Jones*, the CAFC cautioned,

Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. ... Conspicuously missing from this record is any evidence, other than the PTO's speculation ... that one of ordinary skill in the herbicidal art would have been motivated to make the modifications of the prior art salts necessary to arrive at the claimed ... salt.

Jones, at 1943 – 1944. The Examiner has offered no suggestion, other than speculation, that would lead one of ordinary skill in this art to add an oxygenator

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to the Dennehey blood processing assembly supposedly to provide more flexible processing operations.

CONCLUSION

Applicants respectfully submit that with the present remarks, all of the pending claims are allowable over the art of record. Should any minor matters remain prior to the allowance of all of the claims, Applicants request the Examiner to telephone the undersigned attorney to reach prompt resolution thereof.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

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By


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